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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/624,701	07/23/2003	Michael D. Cecchi	H-1362	7072

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EXAMINER

AFREMOVA, VERA

ART UNIT PAPER NUMBER

1651

DATE MAILED: 05/26/2005

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary

Application No.

10/624,701

Applicant(s)

CECCHI ET AL.

Examiner

Vera Afremova

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-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 02 May 2005.
- 2a) ☐ This action is **FINAL**. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 21-27 is/are pending in the application.
- 4a) Of the above claim(s) _____ is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☒ Claim(s) 21-27 is/are rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on _____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some * c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
 2. ☐ Certified copies of the priority documents have been received in Application No. _____.
 3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).
- * See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- | | |
|--|---|
| 1) <input checked="" type="checkbox"/> Notice of References Cited (PTO-892) | 4) <input type="checkbox"/> Interview Summary (PTO-413)
Paper No(s)/Mail Date. _____ |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948) | 5) <input type="checkbox"/> Notice of Informal Patent Application (PTO-152) |
| 3) <input type="checkbox"/> Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08)
Paper No(s)/Mail Date _____ | 6) <input type="checkbox"/> Other: _____ |

DETAILED ACTION

Election/Restrictions

Applicants' election without traverse of group III (original claim 17) in the reply filed on 5/02/2005 is acknowledged.

Original claims 1-20 were canceled by applicants.

New claims 21-27 (filed 5/02/2005) are under examination in the instant office action.

Claim Objections

Claims 21-27 are objected to because of the following informalities:

Claim 21 appears to identify the claimed subject matter by two categories including a "process" and a "procedure" while appropriate claim language should clearly point one category of invention. The language of preamble appears to encompass the claimed subject matter as an in vitro process of manipulating oocyte and fertilized embryo up to embryo implantation stage but the active steps of the whole process/procedure include the implantation step. Thus, the "procedure" as claimed further extends the claimed "process" that is encompassed by preamble of the claim.

Appropriate correction is required.

Claim Rejections - 35 USC § 112

Claims 21-27 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

Claim 21 is rendered indefinite and/or confusing by language of preamble because it is not particularly clear whether in vitro or in vivo methods are claimed.

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Claim 26 is indefinite because it is not clear what is "alamine glutamine" as claimed. The instant claim is interpreted as drawn to incorporation of alanine and glutamine. From the applicants' disclosure it appears that the intended compounds might be "alanine" and "alanyl-glutamine" (page 6).

Claim Rejections - 35 USC § 102

The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless –

(b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

Claims 21-23, 25 and 26 are rejected under 35 U.S.C. 102(b) as being anticipated by Serta et al. ("The developmental potential of mouse oocytes matured in serum-free culture conditions". Human Reproduction. 1995. Vol. 10, No. 7, pages 1810-1815).

Claims are directed to a process for fertilization by using a single (universal) culturing medium formulation wherein the process comprises step of providing a single medium, step of combining the medium with oocyte, step of fertilizing the oocyte in the medium, step of retaining the fertilized embryos in the medium for a time period sufficient to produce implantable embryo and step of implanting embryo. Some claims are further drawn to the medium comprising EDTA and glutamine. Some claims are further drawn to the time period sufficient to produce implantable embryo such as 4 days or 8 days.

Serta et al. discloses a process for fertilization by using a single (universal) culturing medium formulation "mHF-10" comprising alanine, glutamine and antibiotics and supplemented with EDTA (page 1811, col. 1, par. 2, lines 1, 7, 8 and par. 2, line 5). The mHF-10 is

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supplemented with EDTA at each stage of fertilization process including maturation of oocyte (page 1811, col. 1, par. 3, lines 1-5), fertilization of oocyte and development of fertilized embryo up to 4 cells (page 1811, col. 2, par. 5, lines 1-3). Thus, the cited reference clearly discloses the fertilization process comprising step of providing a single medium, step of combining the medium with oocyte, step of fertilizing the oocyte in the medium, step of retaining the fertilized embryos in the medium for a time period sufficient to produce implantable embryo and step of implanting embryo wherein the single medium is used for the whole fertilization process as required by the claimed method. The reference by Serta et al. also discloses (see table II) culturing fertilized embryos in mHF-10 supplemented with EDTA up to blastocysts (8 and more cells).

Thus, the cited reference by Serta et al. anticipates the claimed invention.

Claim Rejections - 35 USC § 103

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

Claims 21-27 are rejected under 35 U.S.C. 103(a) as being unpatentable over Serta et al. ("The developmental potential of mouse oocytes matured in serum-free culture conditions". Human Reproduction. 1995. Vol. 10, No. 7, pages 1810-1815) taken with Zhou et al. ("Effect of antibiotics on development in vitro of hamster pronucleate ova". Theriogenology. 2000. Vol. 54, pages 999-1006), US 6,838,235 (Gardner et al.), Gardner et al. ("Culture and selection of viable

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blastocysts : a feasible proposition for human IVF". Human Reproduction Update. 1997, Vol. 3, No. 4, pages 367-382) and Christie et al. ("Glutamine-based dipeptides are utilized in mammalian cells culture by extracellular hydrolysis catalyzed by specific peptidase". Journal of Biotechnology. 1994, 37: 277-290).

Claims as explained above. Some claims are further drawn to the use of antibiotic such as gentamycin. Some claims are further drawn to additional step of embryo cryopreservation.

Serta et al. discloses a process for fertilization by using a single (universal) culturing medium formulation "mHF-10" comprising alanine, glutamine, antibiotics and EDTA. The antibiotics are penicillin and streptomycin.

The cited reference by Serta et al. is lacking teaching about gentamycin. However, Zhou et al. teaches that penicillin, streptomycin and gentamycin are commonly added to the embryo culture media for antimicrobial purposes with the same effects on embryos, for example: see abstract.

The method disclosed by Serta et al. is lacking cryopreservation step.

However, US 6,838,235 (Gardner et al.) teaches the cryopreservation step for 1-8 cells embryo (Figure 1) during in vitro fertilization procedure (IVF). Although the method of US 6,838,235 (Gardner et al.) encompasses the use of various stage specific media designed for each stage during in vitro fertilization procedure, the medium G 1.2 that is used for development of fertilized embryo comprises EDTA and alanyl glutamine (col. 13, table 5). The cited patent teaches that EDTA supports embryonic development and disables toxins (col.12, lines 38-40). The cited patent also teaches penicillin, streptomycin and/or gentamycin (col.11, lines 19-20) as commonly used antimicrobials during IVF. In addition, the reference by Gardner et al. teaches

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that EDTA is safely used during IVF till the 8-cell stage of development of embryos (page 376, col. 1, par. 2) and that transfer of embryo of 4-cell or 8-cell stage is an accepted global practice for IVF (page 367, col. 2, last par.).

In addition, the reference by Christie et al. teaches that alanyl-glutamine is a substitute for glutamine in mammalian cell culture media because glutamine is susceptible to deamination and produces inhibitory ammonia, because glutamine has short shelf life and cannot be easily sterilized (page 277).

Therefore, it would have been obvious to one having ordinary skill in the art at the time the claimed invention was made to substitute gentamycin for streptomycin and/or penicillin in the method disclosed by Serta et al. with a reasonable expectation of success because gentamycin, streptomycin and penicillin are commonly used antibiotics in the process for IVF as taught and/or suggested by Zhou et al. and US 6,838,235. One of skill in the art would have been motivated to add cryopreservation step to the IVF method of Serta et al. for the expected benefits in preserving implantable embryos for a selected time of implantation and/or for increasing available amounts of implantable embryos.

Thus, the claimed invention as a whole was clearly *prima facie* obvious, especially in the absence of evidence to the contrary.

The claimed subject matter fails to patentably distinguish over the state art as represented by the cited references. Therefore, the claims are properly rejected under 35 USC § 103.

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Any inquiry concerning this communication or earlier communications from the examiner should be directed to Vera Afremova whose telephone number is (571) 272-0914. The examiner can normally be reached from Monday to Friday from 9.30 am to 6.00 pm.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Michael Wityshyn can be reached at (571) 272-0926.

The fax phone number for the TC 1600 where this application or proceeding is assigned is (571) 273-8300.

Any inquiry of a general nature or relating to the status of this application or proceeding should be directed to the Technology center 1600, telephone number is (571) 272-1600.

Vera Afremova

AU 1651

May 24, 2005



VERA AFREMOVA

PRIMARY EXAMINER
